June 30, 2023

CMS-CCSQ Public Comment Letter on United States Core Data for Interoperability (USCDI)+ Quality Draft Data Element List and eCQM Use Case Mapping

On behalf of the Centers for Medicare & Medicaid Services (CMS) and CMS' Center for Clinical Standards and Quality (CCSQ), we submit the following comment on the draft USCDI+ Quality data element list for consideration. We certainly recognize there are many needs and multiple perspectives to consider that must be balanced by the Office of the National Coordinator for Health Information Technology (ONC) and thank ONC for the opportunity to provide comments.

CMS continues to support the development of the USCDI+ Quality domain, which was initiated to build upon USCDI. We believe that together, USCDI and USCDI+ Quality, will be able to define what quality healthcare data patients and providers have access to in a Learning Health System to support clinical care and best outcomes. CMS is committed to digital quality measurement and understands the USCDI+ Quality and USCDI to play a critical role as a foundational framework for this transition. In furtherance of digital quality measurement, CMS provides the following feedback requested by ONC on level of completeness, level of specificity, usability, and frequency of updates to the USCDI+ Quality list.

LEVEL OF COMPLETENESS

CMS is supportive of ONC's initiative to address use case-specific gaps that exist in the current version of USCDI. We are pleased to see several of our priority data elements added to the draft version of USCDI+ Quality list, including Advance Directives, Social Determinants of Health (SDOH), Medications, and Maternal Health data elements. Despite these necessary additions, there are still several critical elements we feel must be added to the draft USCDI+ Quality data element list to support interoperability, patient care, quality initiatives, and access to data. They are also essential for the implementation of current electronic clinical quality measures (eCQMs) in CMS programs.

CMS recommends that all data elements in the Data Element Library (DEL), beginning with the data elements used for quality measures, be included in the USCDI+ Quality Data Element List. We also recognize the need to include additional data elements to fully support patient outcomes and Post-Acute Care (PAC) workflows. As work progresses in this area, we recommend the prioritization of these additional data elements based on industry input and feedback. For example, we recommend including the function and cognition items to inform and better support the related data elements in the USCDI. These data elements found on the PAC assessments are vitally important for patient care and at the time of transitions for patients.

CMS supports the inclusion of data elements related to functional status and has additional recommendations specific to this data class in Appendix A. Current CMS eCQMs also require additional data elements such as Care Plan, Diagnostic Imaging (Test and Report), Facility Information (Facility Name, Facility Identifier including National Healthcare Safety Network (NHSN) Facility Identifier that is facility-specific, Facility Type), Laboratory test result date/time, Medication data elements (Medication Status, Medication Statement), Pregnancy (Delivery date and time associated with a maternal record, Mode of delivery, Blood loss), and Vital Signs (Average Blood Pressure and Head Occipital-Frontal Circumference Percentile (Birth – 36 months)) that ONC should consider adding to the draft USCDI+ Quality data element list. Appendix A has additional detailed comments on the draft data elements.

CMS also notes the importance of the draft USCDI+ Quality data element list to consider data element priorities for future eCQM development and implementation. Note that highest priority data elements

for inclusion in the draft USCDI+ Quality data element list should be those needed to calculate measures currently in quality programs. CMS would like to highlight the following data elements to be considered for future iterations of the USCDI+ Quality version. CMS anticipates they will be essential for eCQMs and potentially even Clinical Quality Measures (CQMs) that may transition to digital quality measures (dQMs) in the future. These are not exhaustive for all future dQM needs but capture and align with CMS' current measurement priority areas.

1. Patient-reported outcomes (PRO) - Patient-reported outcome measures (PROMs) are structured and validated tools which capture objective outcome information directly from a patient that can be condition-specific, procedure-specific, or general (e.g., inclusive of physical and mental health and quality of life). PROMs define the measure outcome and other aspects of patient-reported outcome-based performance measures (PRO-PMs). CMS is moving towards mandatory reporting of PRO-PMs across CMS Quality Programs. Inclusion of PRO-PMs in CMS Quality Programs aligns with the CMS National Quality Strategy Engagement and Outcomes Goals, Meaningful Measures 2.0 Person-Centered Care domain, and goals in the Universal Foundation. Inclusion of PROMs in standardized terminologies such as LOINC, although ongoing, will be crucial to add to USCDI+ Quality to support future CMS priorities.
2. Negation data elements – Some CMS eCQMs currently in the Eligible Clinician and Eligible Hospital programs use negation data elements such as those related to the ObservationNotDone, ServiceNotRequested, ProcedureNotDone, and MedicationNotRequested QI (Quality Improvement)-Core profiles. CMS also anticipates measures in development using these negation concepts and hence, would encourage ONC to consider their addition in the next iteration of the USCDI+ Quality data element list.

LEVEL OF SPECIFICITY

CMS would like to provide the following feedback on the specificity of the data classes and data elements listed in USCDI+ Quality. CMS would like to see the following items further elaborated, for the current data elements in USCDI+ Quality to be usable for the current eCQM measures in CMS programs.

CMS has some concerns about the level of specificity related to the data classes and data elements listed to support adoption in electronic systems. It is unclear if draft USCDI+ Quality data elements are consistent with existing definitions in USCDI or US Core. Overall, CMS recommends providing definitions, related standards, and preferred terminologies associated with the data classes and data elements in the draft USCDI+ Quality data element list. Specific concerns related to clarification of the proposed data element list include:

- Under Health Status Assessments, the data elements including assessment type, value, and time are not clear as to what information is being gathered ("Is a functional status a type of health status assessment? Is a mental cognitive status, a pregnancy status, or alcohol use a type of health status assessment?") and how this data class relates to the USCDI v3 data elements (Functional Status, Disability Status, and Mental/Cognitive Status).
- Additional details on the Referral data element are important to capture, not just whether or not a referral was made.
- Clarification of the data elements included in the Birth Information and Newborn Delivery Information data class is necessary. Specifically, there are data elements that seem duplicative such as Gestational Age and Birth Weight.

Appendix A lists detailed comments on the specificity of the draft USCDI+ Quality data elements.

USABILITY OF USCDI+ QUALITY

CMS appreciates ONC's collaboration with CMS and other stakeholders in developing the draft USCDI+ Quality data element list. It is essential that the data elements for inclusion should prioritize those needed to calculate measures currently in quality programs. CMS currently have eCQMs targeting Eligible Clinicians, Eligible Hospitals/Critical Access Hospitals, and Outpatient Quality Reporting. CMS' eCQMs address a broad range of health topics and patient outcomes. After thorough review of both the draft USCDI+ Quality data element list and the eCQM use case mapping documents by ONC, CMS offers the following feedback on the utility and usefulness of these resource documents to our programs, as well as to measure developers.

CMS appreciates the categorization of the draft USCDI+ Quality data element list by data class, data element, level, and source. There was noted to be some inconsistencies in the level of detail under each data class. For example, Advance Directives data class has very detailed data elements, whereas other data classes do not have the same level of details in data elements (i.e., function, cognition, communication). Currently the USCDI+ Quality data element list contains vague and ambiguous data elements. Given that ONC's intent for the Data Element List is intended to support quality reporting, CMS assessed the number of measures that can be calculated with USCDI+ Quality and estimated that approximately 50% of current eCQMs can be calculated. We anticipate working with ONC to increase the representation of data elements required in current and future eCQMs and dQMs in future iterations of USCDI+ Quality data element list.

There were also discrepancies noted in the categories identified in the USCDI Level and Source columns. It was not always clear how ONC categorized the levels and sources for each data element. For example, some of the Advance Directives for Interoperability (ADI) data elements are attributed to the Post-Acute Care Interoperability (PACIO) workgroup and others are not in the source column. CMS recommends ONC revisit those two columns and reconcile the discrepancies. The source column also requires additional clarification, e.g., why are some data elements "Proposed for USCDI+ Quality" while others are not. An index or definition guide, within the draft data element list publication, defining the categories in the level and source columns would be useful to the public for interpretation. In addition to noting the data class and data element, CMS would recommend the addition of data element definitions and/or preferred terminologies/standards to the final USCDI+ Quality data element list. Finally, CMS recommends an excel version of the final USCDI+ Quality data element list to allow external stakeholders to utilize and review the data more easily.

The USCDI+ Quality eCQM use case mapping publication is a complementary crosswalk specific to eCQMs within CMS quality reporting programs. It is recommended that the final publication specify the CMS program year for the eCQMs that were utilized in the crosswalk. CMS utilized this resource document to review appropriateness of mapping to QI-Core and Fast Healthcare Interoperability Resources (FHIR) of current eCQMs. However, we recommend that the publication should include the data classes listed in the USCDI+ Quality data element list as appropriate since we noted discrepancies between the two publications and have concerns about measure developers unintentionally using data elements from one list over the other. For example, Condition Verification Status, Condition Clinical

Status, and Service Request Intent are in the eCQM use case mapping document but not the Data Element List. We additionally recommend that the eCQM use case mapping document include the draft USCDI+ Quality data elements in addition to the data class. CMS also believes that the non-obtrusive design for representing data classes in the publications should be in the realm of a standards project team working with US Core concepts and consensus-based input from the community about how to best reference FHIR. Publishing the existing use case mapping to QI-Core raises significant risk that some measure concepts might be more efficiently expressed with different QI-Core and FHIR concepts. We recommend that ONC work closely with the CMS eCQM Standards Contractor to evaluate the need for federal level guidance and subsequently design, development and publication of any federal level guidance deemed necessary.

QI-Core Implementation Guide (IG) is well-established, comprehensive and used by measure developers for developing FHIR-based measures and includes more specificity and granularity than the USCDI+ eCQM use case mapping. Not all QI-Core Profiles map directly to USCDI data elements, but instead to USCDI data classes. In addition, not all required fields from QI-Core are listed in the USCDI+ eCQM use case mapping publication. Based on this, CMS recommends that the CMS eCQM Standards Contractor work with the HL7 community to provide the required design in QI-Core to address specific USCDI+ Quality data elements directly in the QI-Core IG. The addition of a footnote in the USCDI+ eCQM use case mapping noting that not all QI-Core Profiles map directly to USCDI data elements, but instead to USCDI data classes can also reduce confusion. In terms of implementation guide support, CMS recommend that the HL7 QI-Core IG support implementation details to the greatest extent possible for a US Realm IG. Suggested recommendations to the USCDI+ Quality eCQM use case mapping publication (see Appendix A) are intended to help reduce burden and better alignment with QI-Core/FHIR.

PROCESS FOR UPDATES TO USCDI+ QUALITY

CMS recognizes that currently the USCDI+ Quality is at an early phase of development. CMS encourages ONC to align their update process and timeline of USCDI+ Quality with the USCDI in the future. However, CMS encourages ONC reconcile the USCDI+ publications across domains and the USCDI prior to publication of the next iteration of USCDI+ Quality to allow for optimal efficiency in data element standardization processes. CMS additionally recommends ONC develop a comprehensive tagging system which will house all the data classes and data elements that fall into the various domains (i.e., USCDI, USCDI+ Quality, and USCDI+ Public Health). Once this database is in place, alignment of the publications of the various domains will be more efficient for external stakeholders.

The public comment period for USCDI+ Quality was 6 weeks this year. CMS recommends ONC for the first couple of iterations that it extend its future public comment period of USCDI+ Quality from 6 weeks to approximately 10-12 weeks (which is currently the public comment period for the USCDI). The extended time will allow sufficient time for stakeholders to conduct their reviews of the updated USCDI+ Quality list and gather relevant and holistic feedback.

ADDITIONAL FEEDBACK

CMS would also like to provide the following feedback to ONC which we encourage ONC to consider.

A. **USCDI and USCDI+ Synchronization**: CMS encourages ONC to synchronize their processes for USCDI and USCDI+ to the extent possible. This will allow alignment and consistency in

the annual update process in upcoming years. In addition, it will lead to less confusion by external stakeholders as they review and provide recommendations and feedback during annual updates. It may be helpful for ONC to provide additional information and resources to the public about how USCDI+ Quality is different from USCDI and other USCDI+ domains.

B. **Implications of USCDI and USCDI+ to others (i.e., QI-Core IG)**: CMS encourages ONC to evaluate and assess in its process the implication of the domains of USCDI and USCDI+ to what's being published for the QI-Core IG. For example, is there anything in USCDI+ Quality that isn't in QI-Core that may result in burden. Also, will USCDI+ Quality include the specificity of QI-Core IGs? Overall, CMS supports alignment of the QI-Core profiles with USCDI+ Quality data elements similar to US Core and USCDI i.e., include indication of which data elements in QI-Core addresses USCDI and USCDI+ Quality.
C. **Comprehensive Tagging System**: Providing guidance on how USCDI correlates with USCDI+ Quality and additional domains will allow for more efficient use of standardized data elements. CMS encourages ONC to have a comprehensive tagging system for all the data elements and data classes in USCDI and the different USCDI+ domains (Quality, Public Health). This will allow for assessment, alignment, and improved usability for the stakeholders.

We are also in support of ONC's endeavors to include quality measurement needs beyond CMS, including CDC's NHSN, National Committee for Quality Assurance (NCQA), and other proprietary quality measures, in order for USCDI+ Quality to support quality measurement more broadly. Further collaboration will also allow for the expansion of USCDI+ Quality beyond eCQMs to include digital quality measurement across the healthcare continuum.

Thank you again for the opportunity to provide CMS-CCSQ comment on the draft USCDI+ Quality data element list. CMS looks forward to continuing to engage with ONC. CMS also continues to have additional data element needs to support our quality measurement programs and look forward to working with ONC on the USCDI+ Quality domain to move forward future priorities.

Thank you,

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Appendix A. Detailed Comments on USCDI+ Quality Data Elements List

USCDI+ Quality Data Class	USCDI+ Quality Data Element	CMS Comment
Advance Directives	Advance Directive Care Experience Preferences	• Advance Directive Care Experience Preferences data element is duplicative of Care Experience Preference data element.
	Care Experience Preference	• Recommend removing Care Experience Preference data element and replacing it with Treatment Intervention Preferences.
	Autopsy Report	• Autopsy Report data element is not a high priority and recommend removal.

Adverse Events		• Include the following elements in this data class:
		  ○ Identify the event as AdverseEvent.event with preferred binding to http://hl7.org/fhir/R4/valueset-adverse-event-type.html.
		  ○ Identify the potentially causative agents as AdverseEvent.suspectEntity.instance referencing Medication resource.
		  ○ Consider adding AdverseEvent.resultingCondition to indicate the outcome of an adverse event as part of the measure.
		  ○ Reference timing as AdverseEvent.recordedDate rather than relevantDatetime since the actual timing of the event is rarely available as structure text if it is available at all.
		• There are discrepancies in the USCDI Level column for some data elements:
		  ○ Date should be Comment level not Level 2.
		  ○ Causality should be Comment level not Level 1.

Birth Information	Gestational Age	• Need clarification if this is defined as at birth or any healthcare encounter.

		• Is this data element related to the maternal or newborn record? • How is this data element different from the Gestational Age at Delivery data element in Newborn Delivery Information data class?
Clinical Tests		• Recommend taking Diagnostic Imaging out of this data class and creating a separate data class with Diagnostic Imaging Test and Diagnostic Imaging Report data elements since the Clinical Test data class is for non-imaging and non-laboratory tests
Communication		• Communication data class and its respective data elements do not seem appropriate for USCDI+. It would be categorized better by using ServiceRequest with ServiceRequest.reasonCode for the condition of concern, and DiagnosticReport for the referral report using DiagnosticReport.basedOn the respective ServiceRequest. • Some eCQMs that use the QDM data element Communication, Performed include the Task resource in the FHIR version with code, executionPeriod, and status.

Encounter Information	Diagnosis	• Most of the encounter elements are reasonable and most align with US Core elements consistent with USCDI version 3. However, Encounter diagnosis should reference the following QDM concepts in the USCDI+ draft use case document:
		  ○ Claim.diagnosis.onAdmission for the *presentOnAdmission* concept
		  ○ Claim.diagnosis.condition with Claim.diagnosis.sequence = 1 for hospital *principal diagnosis* use
		  ○ Claim.diagnosis.condition with Claim.diagnosis.sequence = 1 for ambulatory *primary diagnosis* use

Goals	Functional Ability and Goal: Self-care	• Remove data elements Functional Ability and Goals: Self-care and Functional Ability and Goals: Mobility under the Goals data class and replace them with Self-care Performance and Mobility Performance under the Health Status Assessments data class.
	Functional Ability and Goals: Mobility	

		○ The functional ability goals are more subjective than performance and less indicative of improvement over time for quality purposes. ○ The Goal data elements for Mobility and Self-care are pending removal from quality measures in CMS programs.
Health Status Assessments	Assessment Type	• Unclear what information is being gathered. Is functional status a type of health assessment? Is mental cognitive status, pregnancy status, or alcohol use a type of health status assessment? • Recommend adding additional data elements in this data class: ○ Cognition Performance; Mental/Cognitive Status ○ Communication Performance ○ Health Concerns ○ Functional Status ○ Disability Status ○ Pregnancy Status ○ Smoking Status ○ Substance Use ○ Alcohol Use ○ Physical Activity
	Assessment Value	
	Assessment Time	
Interventions – Non Procedural		• Suggest addition of Date/Time data elements under this data class
Laboratory		• Recommend addition of Date/Time data elements (collected, recorded, reported) under the Laboratory data class
Medical Devices or Equipment	Device Type	• It isn't clear if the USCDI+ element is consistent with existing information in USCDI and US Core. Note that USCDI and US Core address only implantable devices and they do not address personal use devices or other devices used for clinical care yet are not implanted. Since quality measure use cases address personal use devices additional clarity is required for these data elements in USCDI+ regarding the type of device (implantable, clinical use, personal use).
	Devices Used	

Newborn Delivery Information	Type of fetus adverse outcome	• Need additional clarification on these two data elements and the associated standards.
	Birth outcome	
	Neonate/stillborn birthweight and Birth weight	• Recommend including just Birth weight since both data elements measure the same information.

Procedures		• Recommend additional details on procedures and services such as:
		  ○ Treatment Intent
		  ○ Procedure Status
		  ○ Requester information

Problems	Date of Diagnosis	• Need to distinguish between Date of Diagnosis and Recorded Date
Referral	Date of Physician-ordered Start of Care (Resumption of Care)	• Additional details should be included in this data element. It is important to capture, not only the date the referral was made, but additional data regarding the referral.
	Date of Referral	
Symptoms	Symptom	• Consider the use of Condition Encounter Diagnosis, Condition Problem Health Concern or Observation instead of Symptoms data class. ○ Typically, symptoms are 'observations' or 'findings' made by patients and sometimes recorded by patients although mostly entered by clinicians with their interpretations.